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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: INSULIN PRICING LITIGATION	Case No. 2:23-md-3080 (BRM)(RLS) MDL No. 3080
This Document Relates to: *The State of Mississippi, ex rel. Lynn Fitch, Attorney General v. Eli Lilly and Company, et al.* Case No. 2:23-cv-04364 (BRM)(RLS)	

MANUFACTURER DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS

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INTRODUCTION

Mississippi's opposition concedes, as it must, that claims regarding excessive pricing of patented medications are preempted by federal patent law. That concession is fatal to Mississippi's claims regarding glucagon-like peptide-1 receptor agonists ("GLP-1s"), which are *patented* non-insulin medications. In an effort to avoid preemption, Mississippi (the "State") tries to take refuge in a line of Federal Circuit authority that allows state law claims to advance against patent holders that have engaged in bad faith market tactics *by abusing the patent system*. The State invites the Court to make new law and extend that line of cases to general claims of corporate misconduct, without any allegations of unlawful behavior related to the *validity of a patent*. The Court should decline the invitation.

Nor has the State pleaded any other viable claim for relief relating to GLP-1s, which are materially different from the insulin products at the heart of the supposed "Insulin Pricing Scheme" at issue here. The State seeks to elide the plain differences between insulin products and GLP-1s, and even tries to effectively amend its complaint in its opposition brief. These attempts fail, because the complaint is devoid of any factual allegations suggesting wrongdoing as to GLP-1s.

Accordingly, judgment should be granted on the pleadings as to the State's GLP-1 claims.

ARGUMENT[1]

I. The State's Claims as to GLP-1s Are Preempted by Federal Law[2]

A. GLP-1s Are Covered by Patents Owned by Manufacturers

The State's main argument on preemption begins with a remarkable proposition: that there is an absence of proof as to whether the GLP-1 medications are under patent.[3] Opp. at 12-13.

Not so. In the opening brief, Manufacturers identified nearly a dozen patents that cover the GLP-1 products at issue. Br. at 6 n.5. Each patent on its face demonstrates the date of issue, the presumptive owner of that patent (thus showing that each of the GLP-1s is owned by one of the Manufacturers), and the scope of what the patent covers—a GLP-1 agonist molecule that mimics the GLP-1 hormone

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[1] As explained in the opening brief, "[a] Rule 12(c) motion is governed by the same standards as a Rule 12(b)(6) motion." Br. at 8 (citing *Bibbs v. Trans Union LLC*, 43 F.4th 331, 339 (3d Cir. 2022)). The State's citation of *Blanchard Sec. Co. v. Rahway Valley R.R. Co.*, 2004 WL 7329960, at *3 (D.N.J. Dec. 27, 2004) (Opp. at 4) is inapposite because it relies on opinions published before the Supreme Court's *Iqbal* and *Twombly* decisions that cannot be reconciled with those holdings.

[2] Manufacturers separately raised a different preemption argument in their supplemental brief in support of the motions to dismiss filed in this MDL track. Dkt. No. 190-51, at 3-4.

[3] The State also erroneously suggests that Manufacturers "did not assert patent law as a defense." Opp. at 1. In fact, each Manufacturer's answer asserted as a defense that the State's claims are preempted by federal law. *See Mississippi v. Eli Lilly & Co. et al.*, No. 21-cv-00674 (S.D. Miss. Oct. 21, 2021), Dkt. No. 116 at 66; Dkt. No. 117 at 167; Dkt. No. 118 at 74.

produced in the body.[4] These patents correspond to each Manufacturer's GLP-1s that the State seeks to put at issue.

Despite claiming there is an absence of proof, the State does not contest the fact that these patents exist, the date each patent issued, that Manufacturers are assignees and/or applicants on the face of the patents, or that the GLP-1s were under patent during the relevant time period. Nor could it. Indeed, as other complaints in the MDL allege, Manufacturers "continue to enjoy patent protection of their respective GLP-1 agonist molecules through at least 2030, if not later." *E.g.*, Albany County Second Am. Compl. ¶ 258, *In re Insulin Pricing Litig.*, No. 23-md-3080 (D.N.J. Apr. 24, 2024), Dkt. No. 158.[5] Nor does the State dispute that it is proper for the Court to take judicial notice of public records—i.e., the patents at issue. There can be no serious dispute that the GLP-1s are under patent.

[4] These patents—government records whose truth and accuracy cannot be reasonably be questioned—have been publicly available since the date of issue and were easily accessible to the State through a simple search using the patent numbers Manufacturers identified (Br. at 6 n.5). *See* Patent Center, U.S. Patent and Trademark Office, https://patentcenter.uspto.gov/. Manufacturers also attach the relevant patents to this brief for the Court's convenience. *See* Decl. of Andrew Yaphe, Exs. 1-11.

[5] *See also* Lake County Am. Compl. ¶ 257, *In re Insulin Pricing Litig.*, No. 23-md-3080 (D.N.J. Apr. 24, 2024), Dkt. No. 159; King County Second Am. Compl. ¶ 293, *In re Insulin Pricing Litig.*, No. 23-md-3080 (D.N.J. Apr. 24, 2024), Dkt. No. 160.

B. The State's Claims Are Pricing Claims and Therefore Are Preempted

1. The State concedes that pricing claims are preempted

Because the State's claims target patented products, they are preempted by federal law. Binding Federal Circuit law holds that Congress—not the states—is "the promulgator of patent policy." Br. at 9 (citing *Biotechnology Indus. Org. v. D.C.*, 496 F.3d 1362, 1372-73 (Fed. Cir. 2007)).[6] State law claims that seek to penalize high prices are thus preempted as an improper attempt to "re-balance the statutory framework of rewards and incentives" that Congress created. *Id*. at 10 (citing *Biotech*, 496 F.3d at 1373-74). And in its opposition, the State *concedes* that claims based upon a patent holder's setting of prices are preempted by federal patent law. Opp. at 14, 24-26 (conceding preemption applies to "pricing decisions").

2. The State's claims are pricing claims

The State's concession that pricing claims are preempted forecloses the State's claims as to GLP-1s. As explained in the opening brief and the State's own complaint, the State's core theory is that the price of diabetes medications, including GLP-1s, is "excessive," "exorbitant," and "grossly inflated and false" due to the "Insulin Pricing Scheme." Third Am. Compl. ("TAC") ¶¶ 30, 279, 359, 361, 522. The State further alleges that "Manufacturer Defendants artificially and willingly

[6] As Manufacturers have explained—and as the State does not dispute—Federal Circuit precedent on patent law is binding on this Court. Br. at 9 & n.6.

raise their prices," which has led to "outrageously inflated price[s]" from which "Defendants . . . profit immensely." *Id.* ¶¶ 17-18, 20. Indeed, the State's opposition states that its claim is that Manufacturers "repeatedly and in lockstep *raised* . . . *prices*." Opp. at 15 (emphasis added).[7] And the State's counsel has explained that "the States' claims do not seek" to change how Manufacturers report their prices, but instead challenge "*unlawful prices*." Plfs.' Opp'n to Mfrs.' Suppl. Mot. to Dismiss Br., at 5, 7, Dkt. No. 190-53 (emphasis added). These allegations make clear that the State's core allegations are no different from the plaintiffs' contentions in *South-Eastern Pennsylvania Transportation Authority* ("*SEPTA*"), who likewise alleged that the defendant charged "exorbitant prices" and "price gouge[d]." Opp. at 26; 102 F. Supp. 3d 688, 695-96 (E.D. Pa. 2015).

The State argues that it is challenging deceptive conduct, but the only allegations of deception by Manufacturers are grounded in preempted *pricing* conduct—i.e., that "artificially inflated list prices" of the products at issue "were false and completely untethered from the actual prices that Defendants were paid for the drugs," TAC ¶ 435, or that Manufacturers published such "false list prices," *id.* ¶¶ 437-38; *see also id.* ¶¶ 433-34, 436, 439-44, 522. The claim that Manufacturers' prices are "false" because they are too high—which is all that these allegations

[7] *See also* Opp. at 8 (arguing the State stated a claim regarding GLP-1s because "Manufacturers have made the same . . . *price increases* . . . for the GLP-1s" and the "same internal Manufacturer pricing committees *set the prices*") (emphases added).

amount to—is simply the claim that the price is unfair in another guise. As such, it is an impermissible attempt to regulate prices by making an end-run around the bar of the Supremacy Clause. *Cf. SEPTA*, 102 F. Supp. 3d at 703.

Nor can the State get around this by targeting Manufacturers' *publication* of list prices. It is implicit in the right to set prices for a patented product under federal law—conduct that, again, the State concedes it cannot challenge, as any such claim would be preempted (Opp. at 14, 24-26)—that the Manufacturers may make those prices known in the marketplace by "publishing" them. Allowing a plaintiff to challenge the *publication* of prices, while disclaiming any challenge to the prices themselves, would be another improper end-run around Federal Circuit precedent barring state-law claims challenging the pricing of patented products.

Similarly, the State's state-law unfairness and conspiracy claims are inextricably intertwined with the Manufacturers' protected pricing decisions. *See* TAC ¶ 523 (weighing high prices against countervailing benefits to consumers "from Defendants egregiously raising the price of the at-issue drugs" to determine unfairness); *id.* ¶¶ 537, 540 (alleged conspiracy predicated on Manufacturers agreeing to "inflate the prices of insulin and diabetes medications").

Apart from allegations that cannot state a claim—because they pertain to Manufacturers' pricing decisions, and thus are preempted, *see supra* Part I.B.1—the remaining factual allegations supporting the State's claims of unfair or unlawful

conduct pertain solely to the PBM Defendants. *See* TAC ¶¶ 22, 24-26, 303, 309-19, 350, 353-54.

The State cannot ignore its own allegations of a "pricing scheme." *See, e.g.*, *id.* ¶ 13. Those allegations are fatal to its claims because "plaintiffs simply cannot invoke state law to challenge [a defendant's] overall pricing scheme for its patented drugs." *SEPTA*, 102 F. Supp. 3d at 707. As such, the State "cannot use state law to . . . forc[e] [a drug manufacturer] to lower its prices" or seek to "disgorge profits from the sale of [Manufacturers'] patented drugs." *Id.* at 703. Yet that is exactly what the State attempts to do here. TAC at § IX.B (prayer for relief seeking injunctive relief, "restitution" and "disgorgement").

C. The State Does Not Plead "Bad Faith in the Marketplace"

In an attempt to avoid preemption, the State relies on an inapposite line of Federal Circuit cases.[8] Opp. at 21. Those cases hold that state law claims may not be preempted if the plaintiff can show that "the [defendant] patentholder perpetrated fraud before the PTO or acted in bad faith in the marketplace." *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1337 (Fed. Cir. 1998). Because the

[8] The State devotes a number of pages to the threshold question whether patent law may preempt state law claims at all. *See* Opp. at 15-20. Binding Federal Circuit precedent—including the State's own cited case—has resolved that issue. *See, e.g.*, *Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1337 (Fed. Cir. 1998) (explaining that in some circumstances a plaintiff can avoid preemption by pleading fraud on the PTO or "bad faith in the marketplace"); *Biotech*, 496 F.3d at 1365 (holding that a state law regulating price of patented products was preempted).

State does not allege that Manufacturers "perpetrated fraud before the PTO," the only prong of *Hunter Douglas* or its progeny that the State can try to assert is "bad faith in the marketplace." But the State fails to allege this within the meaning of applicable caselaw.

In contrast to *all* of the cases cited by the State, there is no allegation here that any Manufacturer misused its patents or engaged in a reverse payment scheme[9] with a competitor—which is what "bad faith in the marketplace" entails under the Federal Circuit caselaw on which the State relies. Every one of the State's cases (*see* Opp. at 20-23) involved allegations that a defendant (1) knowingly enforced an invalid patent; (2) engaged in sham patent litigation; or (3) engaged in a reverse payment scheme. *See Hunter Douglas*, 153 F.3d at 1322, 1337 (remanding to district court to determine whether allegations of fraud on the PTO and subsequent enforcement of an "allegedly invalid and unenforceable" patent was conduct that showed "bad faith in the marketplace"); *Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1472 (Fed. Cir. 1998) (plaintiffs alleged that the patent at issue was invalid); *Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1355 (Fed. Cir. 1999) (bad faith marketplace conduct defined as a patentee "asserting its patent in the marketplace [despite]

[9] A "reverse payment" generally arises when a patent holder settles a patent infringement lawsuit by paying the accused infringer; in certain circumstances, such activity may be challenged under antitrust law. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 140-41 (2013).

allegedly having known that the patent was unenforceable due to inequitable conduct"). *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 357 (D.R.I. 2017) (plaintiffs alleged fraud on the PTO and subsequent enforcement of the patent "in the marketplace with bad faith"); *In re DDAVP Indirect Purchaser Antitrust Litig.*, 903 F. Supp. 2d 198, 215-18, 224 (S.D.N.Y. 2012) (holding plaintiffs adequately pled "fraud on the PTO and bad-faith enforcement of the patent" through "an invalid Orange Book listing, sham patent infringement litigation, and a sham citizen petition"); *Picone v. Shire PLC*, 2017 WL 4873506, at *14 (D. Mass. Oct. 20, 2017) (state law claim challenging unlawful reverse payment scheme); *Studio 010 Inc. v. Digital Cashflow LLC*, 2022 WL 1215529, at *4 (W.D. Wash. Apr. 4, 2022) (plaintiff "may proceed with its claims that involve the wielding of an invalid patent to interfere with its contractual relations with Amazon.com and to unfairly compete by improperly blocking [plaintiff's] access to the sole marketplace for its products").

Indeed, the *EpiPen* case on which the State relies distinguished *Biotech* and *SEPTA* because the plaintiffs had sufficiently alleged that the defendant engaged in *all three of the types of patent-related conduct* noted above: "patent misuse, reverse

'pay-for-delay' settlements, and sham citizen's petitions." 336 F. Supp. 3d 1256, 1334 (D. Kan. 2018).[10]

By contrast, there are no such allegations of an abuse of the patent system here—as the State in fact *concedes*, emphasizing that Manufacturers' alleged conduct "is wholly separate and unrelated to patent law." Opp. at 4. The State thus invites the Court to create new law and find potential state law liability based on an amorphous form of "bad faith in the marketplace" that is not grounded in controlling Federal Circuit case law. But such a holding would allow any plaintiff who wishes to regulate the price of a patented product to avoid preemption simply by claiming under state consumer protection law that the patent holder did something—anything—wrong. Such a ruling would expand *Hunter Douglas* far beyond its current boundaries. Because the State's allegations do not fall within the *Hunter Douglas* line of cases, its claims as to GLP-1s are squarely preempted under *Biotech*.

II. The State Fails to Adequately Allege Any Unlawful Conduct as to GLP-1s

The opening brief explained that the Mississippi court's motion-to-dismiss decision relied on the State's allegations regarding *insulin*, and that none of those allegations are applicable to GLP-1s. Br. at 14. In opposition, the State contends

[10] The State concedes that it is not asserting an antitrust claim. Opp. at 24. The reverse payment caselaw, which is predicated on paying off a *competitor*, does not apply because the State does not allege that Manufacturers and PBMs are competitors.

that the Mississippi court already considered, and rejected, the lack of allegations against GLP-1s, and that the complaint's allegations as to those products are sufficient. Opp. at 5-11. The Court should reject both arguments.

A. The Mississippi Court Did Not Consider GLP-1s

Nothing in the Mississippi court's cursory decision denying Manufacturers' motion to dismiss suggests that it considered, much less rejected, the arguments presented in this motion. In denying Manufacturers' motion, the court held that "the State delineates each Manufacturer Defendant's alleged participation in the 'Insulin Pricing Scheme.'" *Mississippi ex rel. Fitch v. Eli Lilly and Co.*, 620 F. Supp. 3d 532, 543 (S.D. Miss. 2022) (citing, among other allegations, TAC ¶¶ 265, 267, and 270-71). But as explained in the opening brief, these allegations are specific to *insulin* and thus cannot have served as the basis for that court to reject the arguments presented in this motion. Br. at 13-14. Indeed, the Mississippi court's decision does not so much as *mention* GLP-1s, and the court itself wrote that "[t]his case is about insulin drug prices." 620 F. Supp. 3d at 536; *see also id.* at 537 (finding that the State's complaint "contains in-depth detail about specific insulin drug pricing over time" and highlighting the State's allegation that "the price of certain insulins has increased by more than 1000% since 2003").

Even if the Mississippi court had referred to GLP-1 medications or the handful of allegations that the complaint makes regarding them, the State does not cite any

case law suggesting that Manufacturers are precluded from filing a Rule 12(c) motion on an argument that they did not raise in their Rule 12(b)(6) motion.[11] And in fact, the opposite is true. *See, e.g.*, *Walzer v. Muriel Sibert & Co.*, 447 F. App'x 377, 384 (3d Cir. 2011) (argument not raised in Rule 12(b)(6) motion remains available "in a motion for judgment on the pleadings under Rule 12(c)"). Manufacturers did not raise—and the Mississippi court did not address—the arguments as to GLP-1s presented here. Under black-letter law, Manufacturers may now raise those arguments in this motion.

B. The Allegations in the Third Amended Complaint Regarding GLP-1s Are Insufficient

Unable to point to any specific allegations about GLP-1s in its complaint, the State incorrectly claims its allegations about *insulins* are about GLP-1s. Opp. at 6-9. The State also attempts to amend its complaint through its opposition briefing. *See, e.g.*, Opp. at 9 n.5. The Court should reject its arguments.

Contrary to the State's contention, the Third Amended Complaint does not discuss "Insulins and GLP-1s" in the portions of the complaint that the opposition cites. For example, the opposition contends that "[i]nsulins and GLP-1s cost the Manufacturers very little to produce" (Opp. at 7)—but there are no factual allegations in *any* of the cited paragraphs regarding how much it costs to produce

[11] The State's suggestion that Manufacturers' Rule 12(c) motion is a belated motion for reconsideration (Opp. at 5) is likewise unsupported by any authority.

GLP-1s. *See* TAC ¶¶ 13, 272, 350, 440-41, 523. Similarly, the opposition contends that Manufacturers "make the same Manufacturer Payments to PBMs for insulins and GLP-1s . . . and do so in exchange for preferential formulary placement of those drugs." Opp. at 8. Again, however, the cited paragraphs of the complaint lack *any* factual allegations specific to GLP-1s. *See* TAC ¶¶ 20-23, 315, 317, 350, 386, 390, 397-400, 545. Nor does the Complaint allege that GLP-1s are treated "as interchangeable commodities"—in fact, none of the State's citations support that claim. Opp. at 7 (citing, e.g., TAC ¶ 275, which lists release dates for GLP-1s). At most, the allegations referenced in the State's opposition—apart from the paragraphs and figure identified in the Manufacturers' opening brief—refer generally to "at-issue drugs," and say nothing about GLP-1s in particular. *See*, *e.g.*, TAC ¶¶ 13, 20-23, 386, 432-43, 463-65, 467-68, 471, 475, 522, 545.

Perhaps recognizing the lack of GLP-1-related factual allegations, the State impermissibly attempts to amend the complaint by citing to articles and studies published after it filed the complaint, as well as portions of documents that were not previously included in the complaint.[12] *See*, *e.g.*, Opp. at 7 n.3, 9 n.5. But, as the

[12] Insofar as the State suggests that Manufacturers' *answers* rather than the allegations in its own complaint are what the Court should look to (Opp. at 11 n.7), the suggestion is wrong as a matter of law. *See Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019) ("[I]n deciding a motion for judgment on the pleadings, a court may only consider 'the complaint, exhibits attached to the complaint, matters of public record, as well as undisputedly

Third Circuit has explained, "it is axiomatic that the complaint may not be amended by the briefs in opposition to a [dispositive] motion." *Com. of Pa. ex rel. Zimmerman v. PepsiCo, Inc.*, 836 F.2d 173, 181 (3d Cir. 1988) (cleaned up); *see also Worth v. Unilever United States, Inc.*, 2024 WL 3326039, at *1 n.1 (D.N.J. July 8, 2024) (Martinotti, J.) (declining to "consider the additional factual allegations contained in Plaintiff's Opposition").

The State's other attempts to rebut the Manufacturers' arguments are similarly unavailing.[13] The State misconstrues the point about R&D spending and seeks to manufacture a factual dispute where none exists. Opp. at 10-11. Whether the R&D costs for GLP-1s were in the millions or hundreds of millions (or, in fact, billions) of dollars is not at issue. Rather, the point is that Manufacturers indisputably spent money on R&D to develop GLP-1s, making them different in kind from insulins, which the State alleges are old drugs that had no R&D costs for the time period at issue in this litigation. TAC ¶¶ 270, 273 ("Despite . . . *no new research and*

authentic documents if the complainant's claims are based upon these documents."') (citation omitted).

[13] The State incorrectly suggests that because the Court entered a discovery plan including GLP-1s, the Court already rejected the arguments raised in this motion. Opp. at 11. Not so. The order entering a discovery plan contemplates motion practice on this issue, insofar as it states that discovery would encompass GLP-1s *"[a]bsent Court order* or party agreement otherwise." Case Management Order #10 at § II(D), Dkt. No. 198 (emphasis added).

development, the reported price of *insulins* has risen astronomically over the last (15) years.") (emphases added).

Moreover, the fact that this Court previously considered an argument about new *insulin* drugs in the consumer case has no bearing on this issue. Opp. at 9-10. The plaintiffs in that action filed a second amended complaint that included new allegations regarding the latest generation of insulin products, while claiming that most insulins were functionally interchangeable. *In re Insulin Pricing Litig.*, 2020 WL 831552, at *4 (D.N.J. Feb. 20, 2020). That is not the case here, where the State's own allegations admit that GLP-1s are new and in an entirely different therapeutic class from insulin products. Br. at 14-15. Thus, the fact that GLP-1 drugs are new is directly relevant to their price because, as the State alleges, "research and development costs often make up a large percentage of the price of a drug"—especially given that there are not and could not be allegations that this category of drugs was initially researched "one hundred (100) years ago" (TAC ¶ 270), as the State alleges is true of insulin. Br. at 14-15.

CONCLUSION

For the reasons stated above and in the opening brief, the Court should enter partial judgment on the pleadings in Manufacturers' favor as to the State's claims relating to GLP-1s.

Dated: September 6, 2024

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CERTIFICATE OF SERVICE

I certify that I am Attorney at Law of the State of New Jersey and a Member of the Bar of this Court and that on this date I caused a copy of Manufacturer Defendants' Reply in Support of Motion For Judgment on the Pleadings, and supporting papers, to be served on counsel of record in the above-captioned matter via ECF filing.

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